EXHIBIT C

UNREDACTED
PUBLIC VERSION

Hetero USA, Inc.

1035 Centennial Ave,
Piscataway, NJ 08854, USA
Ph: 732-529-0419
Fax: 732-562-8854

CONFIDENTIAL

July 31, 2024

VIA UNITED PARCEL SERVICE ("UPS")

INGENUS PHARMACEUTICALS, LLC Attention: Chief Legal Counsel 4190 Millenia Boulevard, Orlando, Florida 32839	**DR. REDDY'S LABORATORIES, INC** Attention: Chief Legal Counsel 107 College Road East, Princeton, New Jersey 08540
LEIUTIS PHARMACEUTICALS, LLP Attention: Chief Legal Counsel Plot No. 23, 4th & 5th Floor, VSR Complex Technocrafts Industrial Estate,1st Phase, Balanagar, Hyderabad, India 500037	**DR. REDDY'S LABORATORIES LTD** Attention: Chief Legal Counsel 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, 500034, India
INGENUS PHARMACEUTICALS, LLC Attention: Chief Legal Counsel 100 Ford Road, Suite #9 Denville, New Jersey, 07834	

Re: Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95

Dear Sir/Madam:

In accordance with subsection 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95(a), Hetero USA Inc., the U.S. Regulatory Agent for Hetero Labs Limited Unit – VI[1], provides notice of the following information to you, as the

[1] Hetero Labs Limited Unit-VI is a division of Hetero Labs Limited. This letter and notice refer to Hetero USA Inc., Hetero Labs Limited Unit-VI, and Hetero Labs Limited collectively as "Hetero."

holder of New Drug Application ("NDA") number N212501 for CYCLOPHOSPHAMIDE (Cyclophosphamide) Solution; Intravenous, 500mg/2.5mL (200mg/mL), 1g/5mL (200mg/mL), and 2g/10mL (200mg/mL) or as the patent owner and/or assignee of U.S. patent no. 10,993,952 (the '952 patent), which is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for CYCLOPHOSPHAMIDE SOLUTION; INTRAVENOUS.

In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(I) and 21 C.F.R. § 314.95(c)(1), we advise you that the FDA has received an Abbreviated New Drug Application ("ANDA") for cyclophosphamide Solution; Intravenous, 500mg/2.5mL (200mg/mL), 1g/5mL (200mg/mL), and 2g/10mL (200mg/mL) ("Hetero's ANDA product"). Hetero has received a corresponding Paragraph IV acknowledgement letter concerning the ANDA. The ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A) and contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") to obtain approval to engage in the commercial manufacture, use, or sale of Hetero's ANDA product, before the expiration of the '952 patent.

In accordance with 21 C.F.R. § 314.95(c)(2), we advise that the ANDA submitted by Hetero has been assigned the number 219271 by the FDA.

In accordance with 21 C.F.R. § 314.95(c)(3), we advise that Hetero has received Paragraph IV acknowledgement letter for its ANDA No. 219271 from the FDA.

In accordance with 21 C.F.R. § 314.95(c)(4), we advise that the established name of the drug product that is the subject of Hetero's ANDA is Cyclophosphamide Solution; Intravenous, 500mg/2.5mL (200mg/mL), 1g/5mL (200mg/mL), and 2g/10mL (200mg/mL).

In accordance with 21 C.F.R. § 314.95(c)(5), we advise that the active ingredient in the proposed drug product is known as cyclophosphamide, the strengths of the proposed drug product are 500mg/2.5mL (200mg/mL), 1g/5mL (200mg/mL), and 2g/10mL (200mg/mL) and the dosage form of the proposed drug product is Solution; Intravenous.

In accordance with 21 C.F.R. § 314.95(c)(7), we advise you that the patent alleged to be invalid and/or not infringed in the Paragraph IV certification is the '952 patent, which is listed in the FDA's Orange Book in connection with NDA N212501 for CYCLOPHOSPHAMIDE (cyclophosphamide) Solution; Intravenous, 500mg/2.5mL (200mg/mL), 1g/5mL (200mg/mL), and 2g/10mL (200mg/mL).

We further advise that this notice and letter and detailed statement have been delivered under 21 C.F.R. § 314.95(a) and § 314.95(g).

According to the electronic records of the FDA's Orange Book, the '952 patent has the following expiration date:

Patent Number	Expiration Date[2]
10,993,952	02/15/2036

Hetero alleges and has certified to the FDA that, in Hetero's opinion and to the best of its knowledge, the '952 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in Hetero's ANDA.

In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), Hetero has included with this letter a detailed statement of the factual and legal bases that the claims of the '952 patent are invalid, unenforceable, and/or will not be infringed.

In addition, Hetero has attached an Offer of Confidential Access. Hetero has supplied the information in this letter and its attachments for the purpose of complying with the above-referenced statutes and regulations. Neither Hetero nor its attorneys waive any attorney-client privilege or work-product immunity concerning the subject matter of this communication.

Confidential Notice:

This letter contains proprietary information, which is considered a trade secret. You are not authorized to append this letter to any court pleading (unless under seal) or any other public disclosure. *See In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 667 (D.N.J. 2004); 21 C.F.R. §§ 314.430(b)-(d); *Sw. Energy Co. v. Eickenhorst*, 955 F. Supp. 1078, 1085 (W.D. Ark. 1997), *aff'd*, 175 F.3d 1025 (8th Cir. 1999) (regarding the penalties for public disclosure of proprietary information); 18 U.S.C. § 1832 (Federal Economic Espionage Act).

Service of Process:

The following person is authorized to accept service of process for any patent infringement complaint that may result from this notification (and limited to such a complaint only):

Sam Desai
Director – IP & Legal
Hetero USA, Inc.
1035 Centennial Ave.
Piscataway, NJ 08854
(732) 529-2308
sdesai@heterousa.com

[2] Hetero reserves the right to challenge the accuracy of this expiration date.

Reservation of Legal Rights:

Hetero reserves the right to assert the same, similar, different, or new theories of noninfringement, invalidity, and/or unenforceability, and nothing in this notice letter or detailed statement shall be construed as to limit Hetero's right to make any allegation in any subsequent litigation regarding any issue.

Yours very truly,

HETERO USA, INC.

Sam Desai

Sam Desai
Director – IP & Legal
Hetero USA, Inc.
1035 Centennial Ave.
Piscataway, NJ 08854, USA

Encls: Notice Letter and Detailed Statement
Offer of Confidential Access

Hetero USA, Inc.

1035 Centennial Ave,
Piscataway, NJ 08854, USA
Ph: 732-529-0419
Fax: 732-562-8854

I. Detailed Statement for ANDA 219271

A. Introduction

In accordance with 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), a detailed statement of the factual and legal basis for Hetero's Paragraph IV certification—that the claims of the '952 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in Hetero's ANDA 219271—appears below. Hetero reserves the right to raise additional factual and legal basis concerning noninfringement, invalidity, and/or unenforceability in any litigation or other proceeding that may result from receipt of this letter.

B. Hetero's ANDA Product

Hetero's ANDA product is Solution; Intravenous containing cyclophosphamide as its active ingredient. The strengths of Hetero's ANDA product are 500mg/2.5mL (200mg/mL), 1g/5mL (200mg/mL), and 2g/10mL (200mg/mL).

C. Legal Standards

1. Claim Construction

It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The first step, claim construction, "is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1322 (Fed. Cir. 2001) (citation omitted).

The words of a claim "are generally given their ordinary and customary meaning," i.e., the meaning that the term would have to a person of ordinary skill in the art in question as of the effective filing date of the patent application. *Phillips*, 415 F.3d at 1312-13 (citations omitted). Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, courts look to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean," which include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314 (citations omitted).

When construing a patent claim, a court first analyzes the intrinsic evidence of record—the claims, the specification, and the prosecution history, as such evidence is the most significant source of the legally operative meaning of a claim. *Id.* at 1314-17; *Markman v. Westview Instruments Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd* 517 U.S. 370 (1996). While "words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent

specification or file history." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *see Phillips*, 415 F.3d at 1316.

The Federal Circuit has recognized that a court construing a patent claim may also utilize extrinsic evidence, such as expert testimony and technical dictionaries. *Id.* at 1317. While extrinsic evidence on the issue of claim construction may be referenced, the Federal Circuit has held that it is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Id.* On several occasions, the Federal Circuit has admonished courts construing patent claims for relying on extrinsic evidence because it "poses the risk that [the extrinsic evidence] will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." *Id.* at 1319 (citation omitted). Likewise, extrinsic evidence may not correct errors, erase limitations, or otherwise diverge from the description of the invention as contained in the patent documents. *Aqua-Aerobic Sys., Inc. v. Aerators, Inc.*, 211 F.3d 1241, 1245 (Fed. Cir. 2000).

A patentee cannot recapture in litigation claim scope surrendered—either by amendment or argument—during the prosecution of the patent. *See Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.*, 170 F.3d 1373, 1376-77 (Fed. Cir. 1999). Because "[c]laims may not be construed one way in order to obtain their allowance and in a different way against accused infringers," if a claim must be construed in a particular way to make the claimed subject matter patentable, it cannot be construed differently to cover an accused device if that construction would simultaneously include the prior art. *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995), *cert denied*, 516 U.S. 987 (1995). This principle prevents a patentee from claiming that its patent claims cover subject matter for which the PTO was unwilling to issue a patent. It also gives courts guidance as to what claims or claim elements warrant a narrow scope. When a patentee urges a court to broadly construe or effectively "read out" claim limitations which, if so broadly construed or eliminated, would fail to differentiate a claim from the prior art, courts have a basis for rejecting such claim constructions. *See id.* at 1580-82; *see DeMarini*, 239 F.3d at 1332.

The Supreme Court set aside the Federal Circuit's *de novo* review of every aspect of a lower court's claim construction decision, rejecting that form of review where the district court has resolved factual disputes and made factual findings about the extrinsic evidence. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The Supreme Court held that the "clear error" standard of review applies in those circumstances. *Id.* But it also confirmed that the "ultimate" construction of the claim, even where underlying factual disputes have been resolved, remains a legal conclusion that the Federal Circuit can review *de novo*. *Id.* at 834. The Court also confirmed that *de novo* review is appropriate in cases where the district court reviews only evidence intrinsic to the patent. *Id.*

2. Patent Invalidity

Patent invalidity is a complete defense to a charge of infringement. *See TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir. 2004); *Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001) ("an invalid claim cannot be infringed"); *see also Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998) ("[I]nvalidity operates as a complete defense to infringement for any product, forever."). A patent is invalid if it fails to satisfy any of the conditions for patentability found in 35 U.S.C. §§ 101 *et seq*. Furthermore, a patent claim may be invalid for being an obvious variation of a

prior patented claim under the judicially created doctrine of obviousness-type double patenting.

3. Burden of Proof and Presumption of Validity

Though the burden of proving invalidity rests with the party asserting the defense, a patent is not immune from attack. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1471-72 (Fed. Cir. 1993) (Mayer, J., concurring) (citations omitted). The statutory presumption of validity merely assumes the PTO properly did its job by considering all prior art or other evidence material to patentability. *See Lannom Mfg. Co. v. U.S. Int'l Trade Comm'n*, 799 F.2d 1572, 1575 (Fed. Cir. 1986). "[W]here the PTO has not considered facts relevant to an issue in suit, there is no reason to give deference to its action in issuing the patent and a court may find those facts controlling in determining whether the burden of proof has been sustained." *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 773 n.3 (Fed. Cir. 1983), *overruled on other grounds by SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107 (Fed. Cir. 1985). Thus, "[t]he courts are the final arbiter of patent validity and, although courts may take cognizance of, and benefit from, the proceedings before the patent examiner, the question is ultimately for the courts to decide, without deference to the rulings of the patent examiner." *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 876 (Fed. Cir. 1991).

4. Indefiniteness

Section 112 requires that a patent specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." The Supreme Court has read this provision to require that "a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014).

D. The Orange Book Patent with a Paragraph IV Certification

1. The '952 Patent

The '952 patent, entitled "Stable ready to use cyclophosphamide liquid formulations" issued on May 4, 2021, from U.S. patent application no. 15/551,507 ("the '507 application"), filed on August 16, 2017. This application is the national stage application of international patent application no. PCT/IB2016/050788, filed on February 15, 2016, which claims the benefit of provisional application nos. IN735/CHE/2015, filed on February 16, 2015 and IN3117 / CHE / 2015, filed on June 22, 2015.

a. Claims of the ' 952 Patent

The '952 patent issued with four claims (two independent claims and two dependent claims)"

1. A stable liquid parenteral formulation of cyclophosphamide comprising
i) cyclophosphamide in a concentration of about 12% to about 23% based on total formulation weight;
ii) an ethanol content of about 70% to about 75% based on total formulation weight;

iii) both polyethylene glycol and propylene glycol, wherein a polyethylene glycol to propylene glycol mass ratio is between approximately 1.0:1.0 to approximately 2.0:1.0; and
iv) about 3.4% to about 8.8% based on total formulation weight of polyethylene glycol
v) about 3.4% to about 4.4% based on total formulation weight of propylene glycol
vi) wherein, after storage for 7 days at 40° C./75% RH, decomposition to form any of the following impurities is less than 0.5%:
a) bis(2-chloroethyl)amine hydrochloride;
b) 3-(2-chloroethyl)-2-oxo-2-hydroxy-1,3,6,2-oxadiazaphosphonane; and
c) 3-[2-(2-chloroethylamino)ethyl amino] propyl dihydrogen phosphate dihydrochloride.

2. The formulation of claim 1, further comprising an antioxidant.

3. The formulation of claim 2, wherein the antioxidant is monothioglycerol at concentration of about 0.01% to about 0.02% by total formulation weight.

4. A stable liquid parenteral formulation of cyclophosphamide comprising
i. cyclophosphamide in a concentration of about 23% based on total formulation weight
ii. an ethanol content of about 70% based on total formulation weight;
iii. both polyethylene glycol and propylene glycol, wherein a polyethylene glycol to propylene glycol mass ratio is about 1.0:1.0; and
iv. about 3.4% to about 8.8% based on total formulation weight of polyethylene glycol
v. about 3.4% to about 4.4% based on total formulation weight of propylene glycol, and
vi. about 0.02% based on total formulation weight of monothioglycerol.

b. The Claims of the '952 Patent Are Invalid Under 35 U.S.C. § 112 for Indefiniteness Because the Intrinsic Record Does Not Inform with Reasonable Certainty Those Skilled in the Art About the Scope of the Invention

The term "stable" appears in independent claims 1 and 4. As explained below, the term "stable" render the claims of the '952 patent indefinite under 35 U.S.C. § 112 because a person of skill has no way of knowing the scope of term.

(1) The Specification and Claims Do Not Convey with Reasonable Certainty the Conditions to Determine Stability

The claims of the '952 patent all require "a stable liquid parenteral formulation of cyclophosphamide . . . ." Independent claim 1 contains limitations that limit the amount of three impurities (Bis(2-chloroethyl)amine hydrochloride ("Impurity A"); 3-(2-Chloroethyl)-2-oxo-2-hydroxy-1,3,6,2-oxadiazaphosphonane ("Impurity B"), and 3-[2-(2-Chloroethylamino)ethylamino] propyl dihydrogen phosphate dihydrochloride ("Impurity D") after storage under accelerated conditions, i.e., seven days at 40°C and 75% relative humidity. Independent claim 4, however, does not specify any stability conditions, including storage conditions, time periods, stability measurements, or impurities.

The specification states that "the formulations of the present invention are tested for stability after being stored at 40°C, 75% RH for 7 days." '952 patent col. 3 ll. 14-16. Table 1 of the

'952 patent provides stability data for Impurities A, B, D, E, and G at 40°C, 75% RH for one week. *Id.* col. 4 ll. 15-37.[3]

The specification also uses the term "stable" to describe other conditions. For example, the specification states that the "inventive compositions of Cyclophosphamide were found to be stable when stored at 2°C to 8°C." *Id.* col. 3 ll. 19-20. But unlike the situation for accelerated stability conditions, i.e., 40°C, 75% RH for 7 days, the specification does not provide a time component or list the impurities to measure to determine stability at 2°C to 8°C. Furthermore, the specification does not disclose what constitutes "stable" when stored at 2°C to 8°C.

The claims and specification provide information about at least two different temperatures to obtain the claimed stable liquid formulations of cyclophosphamide: (i) 40°C; and (ii) 2°C to 8°C. But the claims and specification only provide additional information for one of those temperatures, i.e., 40°C, 75% RH for 7 days. A person of skill in the art looking at the claims and specification would not be able to determine what "stable" means with reasonable certainty because there are multiple ways, impurities, and conditions that the claimed composition could be stable.

(2) The File History Does Not Convey with Reasonable Certainty the Conditions to Determine Stability

The file history of the '952 patent does not provide any additional clarification or allow a person of skill in the art to determine what "stable" means with reasonable certainty. Like the specification, the file history discloses stability data for accelerated conditions, e.g., 40°C, 75% RH for 7 days. *See, e.g.*, the April 8, 2020 declaration of Banda Nagaraju; the January 14, 2021 declaration of Kocherlakota Chandrashekhar. But the prosecution history does not provide a time component or list the impurities to measure to determine stability at 2°C to 8°C. Furthermore, the prosecution history does not disclose what constitutes "stable" when stored at 2°C to 8°C.

The person of ordinary skill in the art does not have sufficient guidance to determine whether the "stable" requirement of the independent claims is met. Without adequate guidance as to what should be measured, what storage conditions to use to meet the "stable" limitation requirement under the independent claims, all claims lack reasonable certainty and are invalid for indefiniteness.

E. Conclusion

For at least the reasons detailed herein, the independent and dependent claims of the '952 patent are invalid. Hetero expressly reserves all rights to raise any additional defenses relating to invalidity, unenforceability, and noninfringement, based, among other things, on the facts and information revealed through discovery. Additionally, Hetero expressly reserves the right, if sued, to seek a finding of patent unenforceability due to patent misuse.

[3] Notably, the specification does not list the permissible quantities of impurity C or identify Impurities E and G by their structural formula or chemical name.

II. ABBREVIATED NEW DRUG APPLICATION NO. 219271 OFFER OF CONFIDENTIAL ACCESS IN ACCORDANCE WITH 21 U.S.C. § 355(j)(5)(C)(i)(III)

WHEREAS Hetero has provided notice to Ingenus Pharmaceuticals LLC, Leiutis Pharmaceuticals, LLP, Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories Ltd., (collectively "Ingenus") that Hetero submitted to the FDA an ANDA to obtain approval for Hetero to engage in the commercial manufacture, use, or sale of Cyclophosphamide Solution; Intravenous, 500mg/2.5mL (200mg/mL), 1g/5mL (200mg/mL) and 2g/10mL (200mg/mL), that the ANDA has been received by the FDA and assigned ANDA No. 219271, and that the ANDA contained a Paragraph IV certification with respect to the '952 patent, which is listed in the Orange Book for CYCLOPHOSPHAMIDE.

WHEREAS this document constitutes Hetero's Offer of Confidential Access ("Offer") to that ANDA under 21 U.S.C. § 355(j)(5)(C)(i)(III) which provides:

> The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

WHEREAS Hetero offers to provide Ingenus confidential access to certain information from its proprietary ANDA ("ANDA Confidential Information") subject to restrictions as to persons entitled access to, and on the use and disposition of, the ANDA Confidential Information; and

WHEREAS this document accompanies Hetero's notice and detailed statement under 21 U.S.C. § 355(j)(2)(B) with respect to the '952 patent;

NOW, THEREFORE:

1. In accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III), and subject to the restrictions contained in Section 2 below, Hetero hereby provides Ingenus this Offer to the ANDA for the sole purpose of determining whether to bring an action with respect to the '952 patent;

2. This Offer is subject to the following restrictions as to persons entitled to access and the use and disposition of any information accessed:

A. **Persons Entitled to Access:** Persons entitled to access to ANDA Confidential Information ("Authorized Evaluators") under this Offer are restricted to outside counsel engaged or employed by Ingenus to represent them and the staff of such outside counsel, including paralegal, secretarial, and clerical personnel who are engaged in assisting such counsel, provided that such outside counsel has been identified to Hetero in writing, and provided said outside counsel does not engage, formally or informally, in any patent prosecution for Ingenus or any FDA counseling, litigation, or other work before or involving the FDA.

B. **Materials Accessible by Authorized Evaluators:** A copy of the ANDA Confidential Information, redacted to remove information of no relevance to any issue of patent infringement, will be provided for use by Authorized Evaluators.

C. **Use of the ANDA Confidential Information**:

i. The ANDA Confidential Information and all information derivable from the ANDA Confidential Information be used for the sole and limited purpose of evaluating possible infringement of the '952 patent and for no other purpose. By way of a nonlimiting example only, the ANDA Confidential Information shall not be used: (i) to prepare or prosecute any future or pending patent application by Ingenus; or (ii) in connection with any filing to, or communication with, FDA relating to the ANDA.

ii. Authorized Evaluators shall not disclose any ANDA Confidential Information contained in or derived from the ANDA or any notes, analyses, studies, or other documents to the extent that they reflect any ANDA Confidential Information, to any person other than Authorized Evaluators.

iii. Notwithstanding the provisions of subsections 2(C)(i) and 2(C)(ii) above, Authorized Evaluators shall be permitted to advise Ingenus whether to bring suit alleging infringement of the '952 patent; provided, however, that the ANDA Confidential Information is not disclosed.

D. **Disposition of the Information in the ANDA**:

i. Ingenus agrees that if no suit is filed against Hetero alleging infringement of the '952 patent within 45 days of receipt of this Offer, Ingenus shall cause Authorized Evaluators, within 30 days after the expiration of the 45-day period, to destroy or return to Hetero the ANDA Confidential Information and all notes, analyses, studies, or other documents to the extent that they contain ANDA

Confidential Information, and Ingenus shall promptly notify Hetero that this has been done.

ii. Ingenus agrees that if a suit is filed against Hetero alleging infringement of the '952 patent within the 45-day period:

a) While the litigation is pending, the ANDA Confidential Information and all notes, analyses, studies or other documents to the extent that they contain ANDA Confidential Information, shall be treated as information under the highest level of confidentiality under any protective order entered in the action brought against Hetero, unless the protective order specifies otherwise. Until such a protective order is entered, subsection 2(C)(ii) above continues to apply.

b) No ANDA Confidential Information shall be included in any publicly available complaint or other publicly available pleading.

c) Ingenus shall cause Authorized Evaluators to destroy or return to Hetero the ANDA Confidential Information provided and all notes, analyses, studies or other documents prepared to the extent that they contain ANDA Confidential Information, within thirty (30) days after the final determination of the action brought against Hetero, unless specified otherwise in any protective order entered in the action.

E. Accidental Disclosure: Should ANDA Confidential Information be disclosed, inadvertently or otherwise, Ingenus shall, at their earliest opportunity, by and through Authorized Evaluators, contact Hetero and identify:

i. what has been disclosed;

ii. the individuals to whom such information have been disclosed; and

iii. steps taken by Ingenus and Authorized Evaluators to ensure the ANDA Confidential Information is not further disseminated.

3. Ingenus acknowledges that violation of any provision of this Offer will cause irreparable injury to Hetero and that an adequate legal remedy does not exist. Hetero, therefore, shall have the right, in addition to any other remedies available at law or in equity, to obtain from a court of competent jurisdiction an injunction to prohibit Ingenus from violating the terms of this Offer. Ingenus agrees that in such an action Hetero is entitled to recover any and all damages, costs and expenses, including, but not limited to, all reasonable attorneys' fees, professional fees, and court costs.

4. Should any provision set forth in this Offer be found by a court of competent jurisdiction to be illegal, unconstitutional, or unenforceable, the remaining provisions shall continue in full force and effect.

5. Nothing contained herein shall be construed as a grant of any license or other right to use the ANDA Confidential Information except for the purpose expressly in this Offer.

6. When accepted by Ingenus this document shall constitute the entire agreement of the parties with respect to the subject matter of this Offer and may not be amended or modified except in writing executed by all of the parties.

7. This Agreement shall be construed in accordance with the laws of the State of New Jersey without regard to its conflict-of-law provisions.

8. Nothing in this Offer shall be construed as an admission by Hetero regarding the validity, enforceability, and/or infringement of any U.S. patent. Further, nothing in this Offer shall be construed as an agreement or admission by Hetero with respect to the competency, relevance, or materiality of any such ANDA Confidential Information, document, or thing. The fact that Hetero provides ANDA Confidential Information upon request by Ingenus shall not be construed as an admission by Hetero that such ANDA Confidential Information is relevant to the disposition of any issue relating to any alleged infringement, validity, and/or enforceability of the '952 patent.

9. Ingenus may request access to the ANDA Confidential Information by executing a copy of this Offer where indicated and returning the executed copy to: Sam Desai, Director – IP & Legal, Hetero USA, Inc., 1035 Centennial Avenue, Piscataway, New Jersey, 08854. Following signature, the terms contained in this document shall be considered an enforceable contract between Hetero and Ingenus.

HETERO USA, INC

Sam Desai

Sam Desai
Director – IP & Legal
Hetero USA Inc.

Dated: July 31, 2024

INGENUS PHARMACEUTICALS, LLC

By its authorized agent:

Signature: _____

Name (Print): _____

Title: _____

Date: _____

LEIUTIS PHARMACEUTICALS LLP

By its authorized agent:

Signature: _____

Name (Print): _____

Title: _____

Date: _____

DR. REDDY'S LABORATORIES, INC

By its authorized agent:

Signature: _____

Name (Print): _____

Title: _____

Date: _____

DR. REDDY'S LABORATORIES LTD

By its authorized agent:

Signature: _____

Name (Print): _____

Title: _____

Date: _____